UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,955	11/21/2003	Clayton H. Johnson	40715/294389	4433

7590 07/03/2006

Cynthia B. Rothschild, Esq.
Kilpatrick Stockton LLP
1001 West Fourth Street
Winston-Salem, NC 27101-2400

EXAMINER	
BAUSCH, SARAE L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,955	JOHNSON ET AL.	
	Examiner	Art Unit	
	Sarae Bausch	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *5-16 and 19-26* is/are withdrawn from consideration.

5)☒ Claim(s) *1-3* is/are allowed.

6)☒ Claim(s) *17 and 18* is/are rejected.

7)☒ Claim(s) *4 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted on 04/10/2006.

Election/Restrictions

2. Applicant's election with traverse of group I, claims 1-4 and 17-18 and newly added claim 27 in the reply filed on 04/10/2006 is acknowledged. The traversal is on the ground(s) that searching each of the groups would not prove unduly burdensome. This is not found persuasive because the search for a nucleic acid is not coextensive with the search for methods of detecting H. capsulatum chitin synthase gene, reducing pathogencity of H. capsulatum, inhibiting H. capsulatum chitin synthase gene, or H. capsulatum strain or an inhibitory RNA.

The requirement is still deemed proper and is therefore made FINAL.

3. In response to the restriction requirement, Applicant further elected the specific combination of SEQ ID No. 1, 2, 3, 4, 5, 6, 7, and 8. However, it was noted that the newly amended claims submitted with the restriction requirement do not recite the specific combination of SEQ ID Nos and claims as amended read on individual SEQ ID Nos. As stated in the restriction requirement, applicant was required to elect one specific nucleic acid or a specific combination of nucleic acids. During a telephone conversation with Cynthia Rothschild on 05/17/2006, to clarify if applicant elected the specific combination of all SEQ ID No. 1-6 or one specific SEQ ID No, applicant made a provisional election with traverse to prosecute the invention of Group I, claims 1-4, 17-18, and 27, the specific sequence of SEQ ID No. 1 and the corresponding primers SEQ ID No. 7 and 8.

4. Claims 5-16, 19-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/10/2006.

Priority

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/428135, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Provisional 60/428135 describes the H. capsulatum chitin synthase G gene and fails to provide adequate support or disclose the H. capsulatum chitin synthase 2 gene as required by the claims. As such the priority date of record for claims for the instant application is 11/21/2003.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 17-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 17 and 18 is drawn to a composition comprising an isolated nucleic acid consisting of 21 consecutive nucleic acid sequence of at least one intron of a H. capsulatum chitin synthase gene and an isolated nucleic acid sequence comprising a chitin synthase intron DNA. The recitation of "an" nucleic acid broadly encompasses variants, homologs, and mutants with a minimum of 21 consecutive nucleic acid sequence of any intron within any H. capsulatum chitin synthase gene. While the specification teaches SEQ ID No. 1-6 as introns 1-6 of H. capsulatum chitin synthase 2 gene (see page, lines 14-20), the specification does not teach the nucleic acid sequence of any other intron in any other chitin synthase gene. The claims encompasses wild-type, mutant, variant, and homologs of chitin synthase gene. Therefore, while the specification teaches SEQ ID No. 1-10 as the gene, introns and primers to chitin synthase 2 gene of H. capsulatum, the claims encompass wild-type, mutant, and variant chitin synthase sequences (including other chitin synthase other than chitin synthase 2) that have not been taught or

described by the specification. The specification does not broadly teach "any" 21 consecutive sequence of nucleic acid sequence of "any" intron of chitin synthase gene, the specification teaches only the specific nucleic acid sequences of SEQ ID No. 7 and 8 of intron 1 of chitin synthase 2 gene. The claims encompass any 21 consecutive nucleic acid sequence of any chitin synthase and the specification does not define "any" chitin synthase gene other than the chitin synthase 2 gene defined by SEQ ID No. 9 and 10. In addition the specification does not provide guidance as to what makes a DNA molecule H. capsulatum or chitin synthase intron. The specification does not describe what parts of the sequence make the sequence "H. capsulatum" or "chitin synthase intron". Although the specification does teach primers to SEQ ID NO 1 (page 20 and SEQ ID No 7-8) it does not expressly define specific structural limitations for the broadly claimed nucleic acids. For example, the specification has not taught what makes or identifies a sequence as "intron 1 of chitin synthase 2" or what features would identify such a sequence as "H. capsulatum" and thus the claim encompasses sequences not described by the specification.

While the specification teaches SEQ ID NO 1, 7-8 the specification provides insufficient written description to support the broad genus encompassed by the claims. The instant claims are drawn to undisclosed sequences encoding modification that have not been contemplated. The specification provides insufficient written description to support the genus encompassed by the claim. Absent a written description, the specification fails to show that the applicant was "in possession of the claimed invention" at the time the application for the patent was filed. Further, the genus of polynucleotides comprised by the claim is a large variable genus and also reads on undisclosed genomic sequences. The specification only discloses a selected number of species of the genus; i.e. SEQ ID NO 1, 7-8, which is insufficient to put one of ordinary skill in the art in

possession of all attributes and features of all species within the genus, which include full length genes, mutants, variants, and homologs of chitin synthase from any source. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed genomic sequences, as well as mutants, variants, and homologs from any source at the time the instant application was filed with respect to claims 1-7, 15-24, 50 and 54.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of SEQ ID NO: 1, 7-8; the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d

1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Accordingly, the specification does not provide written description of the invention of claims 17-18 and 27.

8. Claims 17-18 and 27 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended claim(s) contain subject matter that changes the scope of the claim and is not supported in the specification and raises issues of new matter.

The amendment to the claims 17, "isolated nucleic acid consisting of at least 21 consecutive nucleic acid" changes the scope of the claim and recitation of at least 21 consecutive nucleic acid molecules of any intron of any H. capsulatum chitin synthase gene is not supported in the specification and raises the issue of new matter. The specification teaches at least 8 consecutive nucleotides of SEQ ID No. 1-6 (see page 15, lines 1-5) and teaches primers of SEQ ID No. 1 that are 21 nucleotides long, however the specification does not teach 21 consecutive nucleic acid molecules of "any" intron of "any" H. capsulatum chitin synthase gene. The

specification does not provide the critically of 21 consecutive nucleotides of any intron of any H. capsulatum chitin synthase gene. As such, the amendment to claim 17 and 18 is not supported in the specification and raises issues of new matter.

Double Patenting

9. Claim 4 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 1 and 4 recite the same isolated nucleic acid. The recitation of "for detection of H. capsulatum" and "for detection of an active case of histoplasmosis" does not further limit the isolated nucleic acid of claim 1 and 4. The recitation of "for detection of H. capsulatum" and "for detection of an active case of histoplasmosis" is intended use and does not result in a structural difference between the two claimed nucleic acid molecules.

Conclusion

10. Claims 1-3 have been found to be free of the prior art. Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER

Sarae Bausch, PhD.
Examiner
Art Unit 1634